# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

OHNO, Seiji
Ohno & Partners
Kasumigaseki Building 36F
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Chiyoda-ku, Tokyo 100-6036
JAPON

| | |
|---|---|
| Date of mailing *(day/month/year)*<br>06 July 2006 (06.07.2006) | |
| Applicant's or agent's file reference<br>PIK-9002WO | **IMPORTANT NOTIFICATION** |
| International application No.<br>PCT/JP2004/014312 | International filing date *(day/month/year)*<br>22 September 2004 (22.09.2004) |
| Applicant<br>GREEN PEPTIDE CO., LTD. et al | |

1. **Transmittal of the translation to the applicant.**

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

| | |
|---|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland | Authorized officer<br>Yoshiko Kuwahara |
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

| | | |
|---|---|---|
| Applicant's or agent's file reference<br>PIK-9002WO | **FOR FURTHER ACTION** | See item 4 below |
| International application No.<br>PCT/JP2004/014312 | International filing date *(day/month/year)*<br>22 September 2004 (22.09.2004) | Priority date *(day/month/year)*<br>22 September 2003 (22.09.2003) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 | | |
| Applicant<br>GREEN PEPTIDE CO., LTD. | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the report |
| ☐ | Box No. II | Priority |
| ☒ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☒ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

| | |
|---|---|
| | Date of issuance of this report<br>26 June 2006 (26.06.2006) |
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br>Facsimile No. +41 22 338 82 70 | Authorized officer<br>Yoshiko Kuwahara<br>e-mail: pt07@wipo.int |

Form PCT/IB/373 (January 2004)

# PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* |
| Applicant's or agent's file reference<br>PIK-9002WO | FOR FURTHER ACTION<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/JP2004/014312 | 22.09.2004 | 22.09.2003 |

International Patent Classification (IPC) or both national classification and IPC

Applicant
GREEN PEPTIDE CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA/JP | Authorized officer |
|---|---|
| Facsimile No. | Telephone No. |

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2004/014312

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
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**Box No. III** **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 13, 14

because:

☒ the said international application, or the said claims Nos. 13, 14 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Inventions relating to a method for diagnosis of the human body and a method for treatment of the human body are described.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13, 14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/014312

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

   ☒ paid additional fees

   ☐ paid additional fees under protest

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

In documents 1 and 2, a peptide consisting of 9 or 10 HCV-originated amino acid sequences, which is an MHC class I and MHC class II binding motif, is described, and a peptide consisting of an amino acid sequence identical to that of SEQ ID NO.: 1 of the invention of this application is identified.

Since an HCV-originated peptide capable of activating both the cell immunity and the hormonal immunity were publicly known before this application was filed, the mere provision of the peptide cannot be a special technical feature in the sense of PCT Rule 13.2. SEQ ID NOS.: 1-8, 16, 20 and 38 described in claims do not share an amino acid sequence (important structural element).

Thus, the inventions relating to SEQ ID NOS.: 1-8, 16, 20 and 38 described in the claims cannot be a group of inventions so linked as to form a single general inventive concept, and the 11 inventions corresponding to SEQ ID NOS.: 1-8, 16, 20 and 38, respectively, are considered to be described in the claims of this application.

Document 1: JP, 8-507525, A (Cytel Corp), 13 August, 1996 (13.08.96), & WO, 94/20127, A1, & EP, 703783, A1
Document 2: JP, 2002-520000, A (Epimmune Inc.), 9 July, 2002 (09.07.02), & WO, 99/58658, A2, & EP, 1078092, A2

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-12, 15-18

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/014312

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 9 | YES |
| | Claims | 1-8, 10-12, 15-18 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-12, 15-18 | NO |
| Industrial applicability (IA) | Claims | 1-12, 15-18 | YES |
| | Claims | | NO |

2. Citations and explanations:

(Invention Relating to SEQ ID NO.: 1)
Document 1: JP, 8-507525, A (Cytel Corp), 13 August, 1996 (13.08.96), & WO, 94/20127, A1, & EP, 703783, A1
Document 2: JP, 2002-520000, A (Epimmune Inc.), 9 July, 2002 (09.07.02), & WO, 99/58658, A2, & EP, 1078092, A2
Document 3: US, 2002/0119127, A1 (Epimmune Inc.), 29 August, 2002 (29.08.02), & WO, 02/83714, A2

Claims 1-8, 10-12 and 15-18

The subject matters of claims 1-8, 10-12 and 15-18 do not appear to be novel or to involve an inventive step in view of documents 1-3 cited in the ISR.

In documents 1-3, a peptide consisting of 9 or 10 HCV-originated amino acid sequences, which is an MHC class I and MHC class II binding motif, is described, and a peptide consisting of an amino acid sequence identical to that of SEQ ID NO.: 1 of the invention of this application is identified [document 1 (pages 86 and 100), document 2 (page 98) and document 3 (FIGURE 18B)].

Claims 9, 12 and 15-18

The subject matters of claims 9, 12 and 15-18 do not appear to involve an inventive step in view of documents 1-3 cited in the ISR.

It is obvious to a person skilled in the art that a virus-originated immunogenic peptide produces an antibody and can be used as a diagnostic reagent and a drug.

(Concerning Inventions Relating to SEQ ID NOS.: 6 and 7)
Document 4: JP, 2003-509465, A (Epimmune Inc.), 11 March, 2003 (11.03.03), & WO, 01/21189, A1, & EP, 1200109, A1

Claims 1-8, 10-12 and 15-18

The subject matters of claims 1-8, 10-12 and 15-18 do not appear to be novel or to involve an inventive step in view of document 4 cited in the ISR.

In document 4, it is described that a peptide consisting of 9 or 10 HCV-originated amino acid sequences, which is an MHC class I and MHC class II binding motif, induces a cytotoxic T lymphocyte (CTL) response and a helper T lymphocyte (HTL) response, and a peptide consisting of amino acid sequences identical to that of SEQ ID NOS.: 6 and 7 of the invention of this application is identified [document 4 (Table XVIII on page 214)].

Claims 9, 12 and 15-18

The subject matters of claims 9, 12 and 15-18 do not appear to involve an inventive step in view of document 4 cited in the ISR.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

It is obvious to a person skilled in the art that a virus-originated immunogenic peptide produces an antibody and can be used as a diagnostic reagent and a drug.
(Invention Relating to SEQ ID NO.: 8)
Document 5: JP, 8-500106, A (Cytel Corp), 9 January, 1996 (09.01.96), & WO, 94/03205, A1, & EP, 656788, A1
Document 6: WO, 01/70772, A2 (Fabre Medicament SA Pierre), 27 September, 2001 (27.09.01), & EP, 1305332, A2, & JP, 2003-528112, A
Document 7: JP, 2002-507397, A (Epimmune Inc.), 12 March, 2002 (12.03.02), & WO, 99/45954, A1, & EP, 1064022, A1

Claims 1-8, 10-12 and 15-18

The subject matters of claims 1-8, 10-12 and 15-18 do not appear to be novel or to involve an inventive step in view of documents 5-7 cited in the ISR.

In documents 5-7, a peptide consisting of 9 or 10 HCV-originated amino acid sequences, which is an MHC class I and MHC class II binding motif, is described, and a peptide consisting of an amino acid sequence identical to that of SEQ ID NO.: 8 of the invention of this application (peptide 2.0037 of document 5 (page 110, 23(e)) and SEQ ID NO.: 315 of document 6) and a very similar peptide (peptide 2.0170 of document 7 (Table 4 (series) on page 50) are identified.

Claims 9, 12 and 15-18

The subject matters of claims 9, 12 and 15-18 do not appear to involve an inventive step in view of documents 5-7 cited in the ISR.

It is obvious to a person skilled in the art that a virus-originated immunogenic peptide produces an antibody and can be used as a diagnostic reagent and a drug.

(Invention Relating to SEQ ID NO.: 3)
Document 8: JP, 2002-510038, A (Innogenetics N.V.), 2 April, 2002 (02.04.02), & WO, 99/50301, A2, & EP, 947525, A1
Document 9: JP, 2001-522599, A (Innogenetics N.V.), 20 November, 2001 (20.11.01), & WO, 99/24466, A2, & EP, 1028972, A2

Claims 1-12 and 15-18

The subject matters of claims 1-12 and 15-18 do not appear to involve an inventive step in view of documents 8 and 9 cited in the ISR.

Documents 8 and 9 describe an HCV-originated epitope, and a peptide fraction including an amino acid of SEQ ID NO.: 3 of the invention of this application (C2a peptide of document 8 (Table 1 (series) on page 24) and SEQ ID NO.: 21 of document 9 (page 38)).

A person skilled in the art could have easily removed the terminal of the peptide fraction within the bounds of allowing a shape as an epitope to be maintained.

(Invention Relating to SEQ ID NO.: 4)
Document 10: WO, 02/04484, A2 (MedMira Inc.), 17 January, 2002 (17.01.02), & EP, 1328811, A2
Document 11: WO, 02/55548, A2 (Innogenetics N.V.), 18 July, 2002 (18.07.02), & EP, 1463753, A2, & JP, 2004-525885, A, & US, 2003/0147918, A1

Claims 1-12 and 15-18

The subject matters of claims 1-12 and 15-18 do not appear to involve an inventive step in view of documents 10 and 11 cited in the ISR.

Documents 10 and 11 describe an HCV-originated epitope, and a peptide fraction including an amino acid of SEQ ID NO.: 4 of the invention of this application (MDL-13 peptide of document 10 (Table 1 on page 33) and SEQ ID NO.: 59 of document 11).

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

A person skilled in the art could have easily removed the terminal of the peptide fraction within the bounds of allowing a shape as an epitope to be maintained.

(Invention Relating to SEQ ID NO.: 16)
Document 12: WO, 93/11158, A2 (Akzo N.V.), 10 June, 1993 (10.06.93), & AU, 9230847, A
Document 13: JP, 3-228681, A (Juridical Foundation the Chemo-Sero-Therapeutic Research Institute), 9 October, 1991 (09.10.91) (Family: none)
Document 14: JP, 8-73497, A (Tonen Corporation), 19 March, 1996 (19.03.96) (Family: none)

Claims 1-12 and 15-18

The subject matters of claims 1-12 and 15-18 do not appear to involve an inventive step in view of documents 12-14 cited in the ISR.

Documents 12-14 describe an HCV-originated epitope, and describe a peptide fraction including an amino acid sequence of SEQ ID NO.: 16 of the invention of this application (Inhl-16 peptide of document 13 and SEQ ID NO.: 4 of document 14) and a peptide fraction (document 12 (Figure 3)) very similar to the amino acid sequence of SEQ ID NO.: 16 of the invention of this application.

A person skilled in the art could have easily removed the terminal of the peptide fraction within the bounds of allowing a shape as an epitope to be maintained.

(Inventions Relating to SEQ ID NOS.: 2, 5, 20 and 38)

The subject matters of claims 3-12 and 15-18 do not appear to involve an inventive step in view of documents 1-7 cited in the ISR.

Documents 1-7 describe a large number of peptides consisting of 9 or 10 amino acid sequences, which are MHC class I and MHC class II binding motifs. On the other hand, the peptide "having amino acid sequences having 70% homology with SEQ ID NOS.: 2, 5, 20 and 38 of the invention of this application, and the polypeptide "including such a peptide" do not have an effect that could not have been anticipated by a person skilled in the art.

Claim 2

The subject matter of claim 2 (only SEQ ID NOS.: 2, 5, 20 and 38) appears to be novel and to involve an inventive step in view of the documents cited in the ISR.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/014312

**Box No. VIII** **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

(1) Claim 1 is unclear, since the peptide is not adequately identified as a chemical substance.

(2) The specification is unclear, since on page 12, the descriptions of the specification and drawings of Japanese Patent Application No. 2003-330258 are incorporated by reference in their entirety.